Mooc Application Related to Shared decision making in Bariatric Surgery

The MARS Trial

Objectives and purpose of the research

The primary aim of this study is to undertake a randomised controlled trial of the effect of MOOC patient education modules versus standard protocol patient education and consent on patient recall and satisfaction for shared decision making in bariatric surgery.

The secondary aims of this study will include:

- A qualitative review of the feasibility of MOOC creation in bariatric surgery and its use as a surgery decision aid for patients as a means to expand to other surgical specialties
- Engaging patients and clinicians in the creation of patient oriented decision tools

The research group hypothesise that:
- patient recall and understanding will be enhanced with MOOC led patient education compared to standard patient education for consent
- MOOCs will be a feasible and reproducible platform for creation of patient related interactive content and be acceptable to patients.
- MOOCs will allow a more tailored shared decision making process by highlighting areas of less understanding and encouraging patients to ask relevant questions in the clinic by bringing up points for discussion.
- MOOCs will be valuable in the shared decision making process to clinicians to demonstrate mutual understanding of the surgical condition and surgery proposed

Background and rationale

The consenting process is not merely signing a form to allow an intervention or procedure to happen but is a process that allows the sharing of information regarding the procedure which concerns its benefits, risks and alternatives. Shared decision making can therefore be defined as a two way process that allows patients to express their preferences and opinions regarding pros, cons and alternatives to a particular procedure and allows the clinician to explain these pros, cons and alternatives on an individual basis. The Royal College of Surgeons has produced guidelines on shared decision making and consent, highlighting the paradigm shift that has occurred in the last ten years in this regard from what was traditionally a more paternalistic unidirectional approach (1). The College guidelines go further in recommending clinicians to encourage patients to seek web based and other information. Despite this and the favorable view of both clinicians and patients towards shared decision making, it is clear that it is still in its infancy as highlighted in a 2018 systematic review by de Mik et al (2). This systematic review of thirty two studies highlights a need for further research with regards to interventions to improve shared decision making.

Moreover, reviews from the NHS litigation authority claims against 11 surgical specialties over a ten year period revealed that failure to adequately consent was one of the three leading causes of claim with an estimated £1.5 billion paid out to claimants from 2004 to 2014. It is in the clinician's and patient's benefit for the decision making process to be robust and adequate and that resources are provided for this (3).

It is clear to clinicians that the shared decision making process needs to evolve in practice. Patients need to be empowered to seek accurate information and be provided with the resources to allow an informed shared decision making process. This is where the researchers of this study believe Massive Open Online Courses (MOOCs) can play a role.

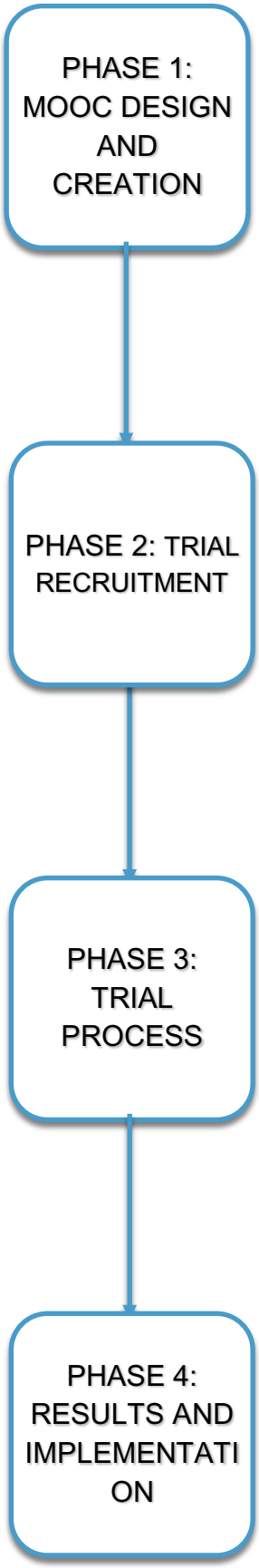
Massive Open Online Courses (MOOCs) have existed as a disruptor in the education sector (5). They are defined as free online courses which can be accessed by anyone at any time. They provide short courses to a large unrestricted and undifferentiated number of students, on a flexible basis on a wide variety of subjects. Courses are considered more democratic and accessible than traditional higher education courses as they are more inclusive, largely have no pre-requisites and usually free of charge from a range of higher education institutions. The use of MOOCs in patient education is limited and understudied but can be a powerful and much more accessible and interactive platform than patient leaflets or other existing media for patient information (6). MOOCs can also reduce the need for human capital, allow for templates for creation of further courses/patient decision aids and reduce costs of information dissemination. They are also more sustainable and interactive than traditional patient leaflets, can be updated easily and usually involve small tests and certificates as proof of completion as well as being more environmentally friendly. Where MOOCs test understanding, clinicians can utilise test scores in areas of deficient understanding to tailor the consultation and consent appropriately to what the patient would like to understand better.

Thus the trial aims to cover two main unexplored concepts. The first is the feasibility of engaging patients and clinicians in MOOC creation for bariatric surgery. The second is trialing the MOOC in terms of utility as a patient decision aid versus traditional methods of patient information dissemination which in our case is a patient leaflet and traditional consenting process. Utility would be assessed by means of ability to recall information and also patient satisfaction with the process.

Preliminary work and previous literature

The researchers have already performed and published a preliminary systematic review which was registered on the PROSPERO database (CRD: CRD42019132188). This preliminary work looked at the quality and readability of online patient literature pertaining to bariatric surgery using validated scoring tools such as Fleisch Kincaid, IPDAS and DISCERN. This systematic review demonstrated that the average readability of all sources extracted was higher than that recommended for patient literature. Only half of the studies contained had received HONcode or Information Standard accreditation, suggesting a quality marker for the content. On grading of quality and content, across validated scoring tools, no source achieved the minimum recommended level (4).

This preliminary work helped us on two fronts. The first was establishing a need for better quality patient information for shared decision making due to the poor quality of current offerings. The second was that it helped us educate ourselves on the various scoring tools and validation requirements for providing readable and high quality patient content, essentially by understanding how to grade the quality of patient information, we understood the toolkit for its creation.


PHASE 1: MOOC DESIGN AND CREATION
PHASE 2: TRIAL RECRUITMENT
PHASE 3: TRIAL PROCESS
PHASE 4: RESULTS AND IMPLEMENTATION

Methodology

Study Phases

Phase 1:
Phase one of the study will involve MOOC design and creation. This phase will involve a six month period to create the audiovisual and text material for the MOOC. This phase will involve three stages:

1.a Stage one:
Material creation using a multidisciplinary team of dieticians, bariatric nurse specialists and surgeons. A patient team made up of volunteer patients who have previously been involve PPI (patient public involvement involvement) in our unit and have experience of giving feedback for research. This group will help test that the material is understandable and help produce some of the video material from a patient perspective.

The MOOC will involve modules patients will work through and modules will take no longer than three weeks to complete with a total time of 3 hours of material. The three modules will cover pre-operative information needed pertaining to workup, liver diet and endoscopy, operative details and complications as well as post operative information in an interactive and audiovisual format.
This stage of the study has already been completed and the MOOC can be accessed on https://marsbartrialstsft.thinkific.com/courses/bariatric -surgery -for -patients

We are seeking ethical approval for the remainder of the study which is trial recruitment and PPI focus group.

1.b Stage two:

This is a MOOC testing stage. Audio-visual material will be transcribed and all written material will be tested for readability using the Fleisch-Kincaid readability tool and the PEMAT A-V tool will be used with both one patient tester from the PPI team and one medical person using the tool to assess all the material. The MOOC will also have a pilot run with ten patients testing the modules and giving feedback before it goes live to the trial.

Phase 2:

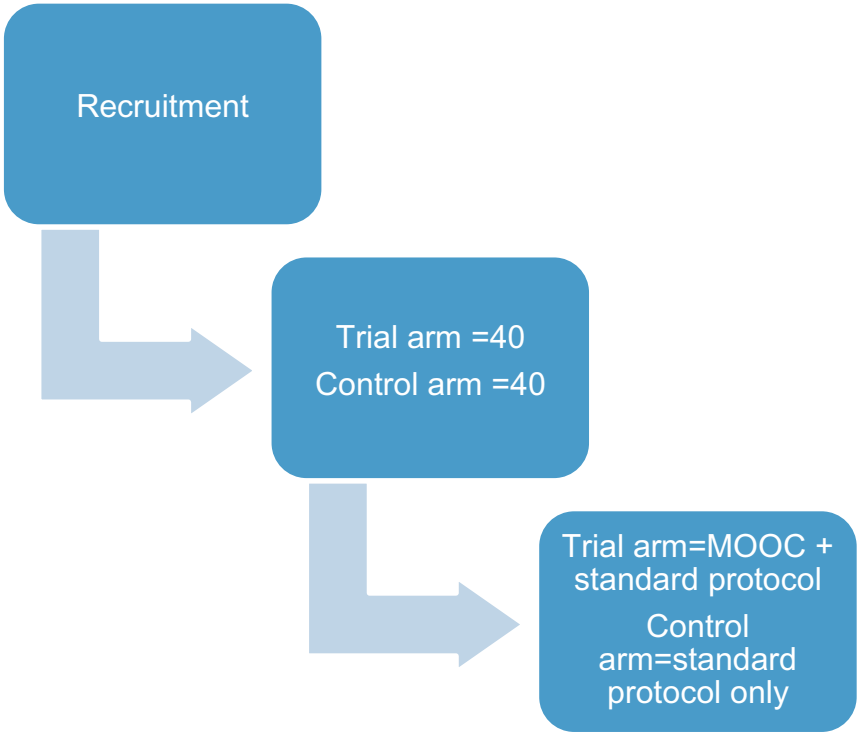
The second phase of the study involves trial recruitment which is outlined in detail below.

Phase 3:

The third phase involves the trial process which is outlined below

Phase 4:

The fourth phase is trial results and implementation which is also detailed below.



Study Design

The study design is a randomised clinical trial with two arms. The trial will be double blinded to the consultant surgeon seeing them in clinic and to the assessor of recall but not blinded to the patient. Power calculations showed that to detect an improvement of 20% in the primary outcome measure of recall in the experiment group, with a two-sided 5% significance level and a power of 80% and a drop out rate of 10%, a sample size of 40 patients per arm is necessary.

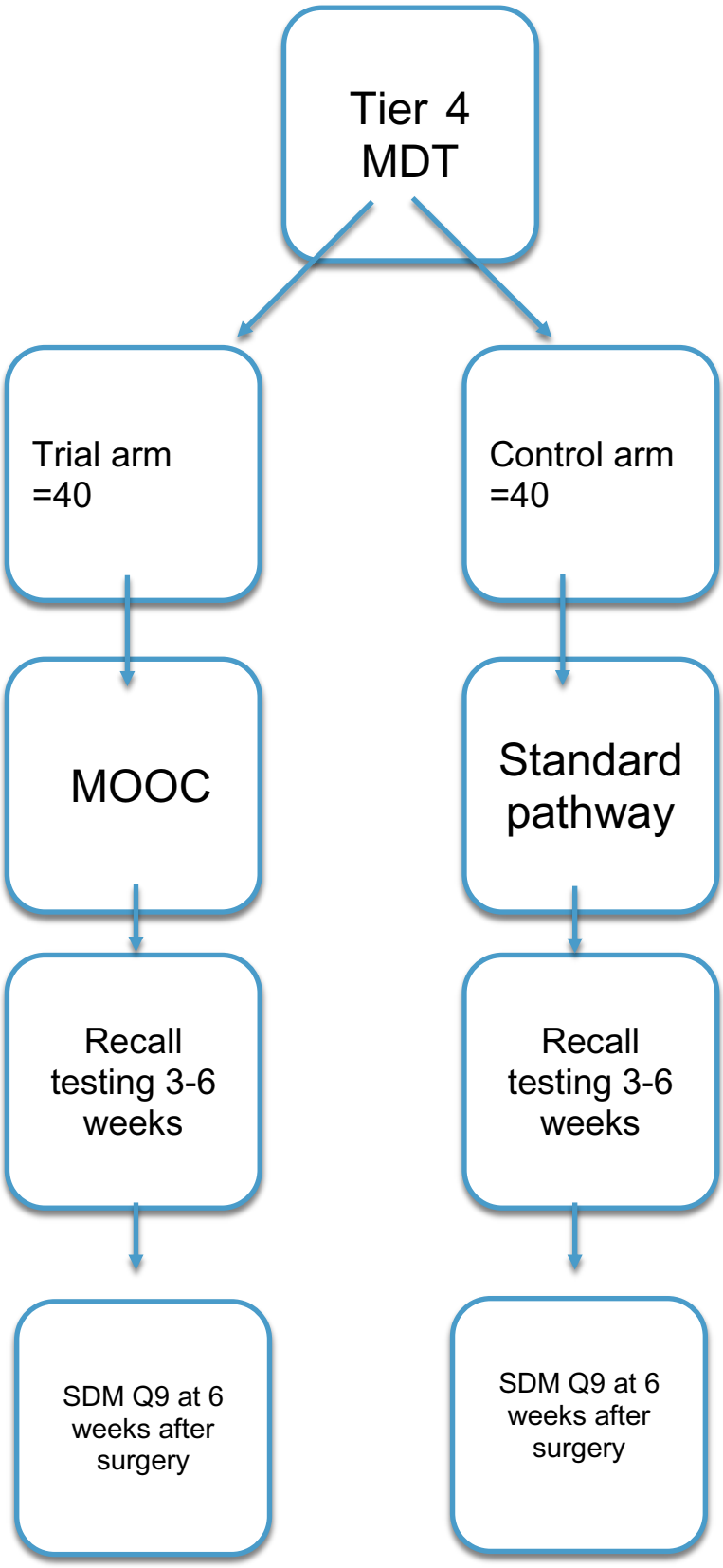
In most bariatric units in the UK, all patients suitable for bariatric surgery undergo a standardised Tier 3 programme which involves dietary education, psychological assessments and patient education with regards to weight management. Consideration for bariatric surgery (Tier 4) is for those patients who have successfully completed the tier 3 programme and been discussed at the Tier 4 MDT.

In the trial arm, we aim to recruit at least 40 patients who are eligible for bariatric surgery as defined by approval by the Tier 4 MDT and are awaiting consultant review in clinic for consent. These patients, after identification, recruitment and consent for trial participation, will be given a login and password for access to the patient education MOOC in the envelope which randomised them. The MOOC will be need to be completed prior to their clinic appointment. MOOC test results will be available to the research team on completion and entered into the REDCap database. Patients recruited to this arm will be asked not to unblind themselves to the consultant consenting them in clinic or to the blinded assessor of recall and will also be given the standard patient information leaflet during their consultation as per protocol.

In the control arm, at least 40 patients recruited will not be given the MOOC login or password in the envelope but will undergo the standard consultant clinic appointment for listing and consenting and

will be given the standard patient information leaflet which is our standard protocol in the Tier 4 pathway.

Patients in both arms of the trial will be called by a blinded member of the research team (the assessor) to check recall of information 3-6 weeks after recruitment in the trial. At 6 weeks after their surgery, both arms will be asked to complete the validated SDM-Q -9 questionnaire.


Tier 4 MDT
Trial arm =40
Control arm =40
MOOC
Standard pathway
Recall testing 3-6 weeks
Recall testing 3-6 weeks
SDM Q9 at 6 weeks after surgery
SDM Q9 at 6 weeks after surgery

Study Site

The study will be a single centre trial based in the South Tyneside and Sunderland NHS Foundation Trust. The regional bariatric centre based at Sunderland Royal Hospitals is one of the largest in the UK with over 1000 bariatric referrals per annum. We believe the volume of bariatric surgery and team expertise as well as links to the University of Sunderland, makes us best placed to run this trial.

Subject Selection

Inclusion Criteria

Patients 18 years of age and over who are able to read and write

Patients who are eligible for tier 4 bariatric services having completed a Tier 3 weight loss programme (standard criteria for eligibility to have bariatric surgery)

Exclusion Criteria

Patients without access to smartphone or a computer are also excluded

Patients who are having revisional bariatric surgery

Patients must also have a suitable grasp of the English language in order to participate.

Randomisation Method and Blinding

Patients who are eligible and consented to participate in the study will be randomised to either the trial group or the control group with use of the sealed envelope method. The randomisation will be blocked with use of random permuted blocks in groups of two, four, or six to help ensure that the groups are balanced. A piece of paper that has the phrase “MOOC” or “Control” will be placed inside an envelope. MOOC patients will have the login and password in the envelope for access.

Withdrawal

At the time of consent, participants will be informed that their participation in this research is voluntary and that they may discontinue participation without penalty at any time. All data will be included in the final analysis on an intention to treat basis.

Ethical Approval

Application for ethical approval will be made via the trust research ethics committee as well as the NHS HRA via an IRAS application as the research involves human subjects.

Main Outcome Measures

The main outcome measures will be recall which will be tested by phone call to all patients in the trial by a blinded assessor. A 10 item questionnaire regarding the operation will be asked over the phone or face to face to both control and arm groups by a member of the research team three to six weeks after trial recruitment. Satisfaction with the shared decision making process will be tested using the SDM Q9 questionnaire sent by post 6 weeks after surgery. Data will be recorded on the REDCap database using an anonymised study ID.

Process Measures

The process measures will be to understand firstly patient acceptability to MOOC education. We will perform this by means of a voluntary patient focus group after unblinding which will allow us to ascertain patient reactions to the MOOC as well as any suggestions for improvement in order to allow this to be rolled out for all patient groups. A further process measure will be a qualitative review of consultant and MDT team attitudes to MOOC creation and MOOC education by means of a focus group.

Patient and Public Involvement:

There will be two meetings for patient and public involvement. The first pre-trial meeting will involve patient representatives' views on the trial and conduct as well as acceptability of the MOOC platform and will involve ten patients. The second pre-trial meeting will occur after MOOC creation and will gain feedback on the audio-visual material. The audio-visual material will also include a patient interview who will give their perspective on surgery. At this stage, the prototype phase of the MOOC will be edited to incorporate the changes suggested. A separate pilot test will be done after this to test the material on ten patients prior to trial recruitment to check understanding and quality. The material will be tested using the PEMAT-AV scale and transcribed and entered into the Fleisch-Kincaid tool to check quality and readability.

Training and Records Retention:

All members of the research team will be educated on the study protocol at a meeting set up for training purposes. All members of the research team will be able to ask questions at this education session and after the education session to ensure they are comfortable with all aspects of the study protocol. Members of the research staff that will be using REDCap (Research Electronic Data Capture) will be trained on how to use this database.

Subjects will be assigned a unique study ID that will be used on all case report forms and database reporting. Any hard copies will be maintained in a locked cabinet in a locked office by a member of the research team. Data will be stored in REDCap which is HIPPA compliant, encrypted, and password protected. Work will only be done on password protected

Anticipated Outputs, Benefits and Outcomes

Main Outcomes:

The main anticipated outcomes is that the trial will demonstrate improved understanding for the trial arm of the group compared to the control group with regards to the procedures they are consenting for. We anticipate that recall will be improved from the shared decision making process in the trial arm. With regards to patient satisfaction with the shared decision making process, we anticipate a significant difference favouring the trial arm. The main outcome measures will be recall testing using a 10 point test on the bariatric procedures and the SDM Q9 questionnaire results.

Secondary Outcomes:

We also anticipate that the qualitative element of the study will show that patients find MOOC use acceptable and easy. We will also use this interview process after the un-blinding to explore ways in which the MOOC can be improved in order for it to be applicable to other surgical procedures and specialties. A separate focus group will interview clinicians/patients and the wider MDT team on their views on the MOOC as well as their participation.

We perceive the main strengths of this study and its outcomes are the demonstration of the feasibility of creation of patient related content on a MOOC platform that is easily reproducible and rolled out for use for all bariatric surgery patients. In addition, as a high volume unit, we believe we are best placed to roll out this initiative.

Benefits:

Locally:
The researchers of this study believe that patients should be suitably consented and be able to participate in the shared decision making process. Improving our own local process by using a MOOC platform which we can re-use even after the trial period will mean the trial will have direct impact and patient benefit even beyond the trial period. An indirect outcome from the trial will mean that we have a closer scrutiny of our shared decision making processes with regards to bariatric surgery and a heightened awareness of patient understanding and recall. By having a post trial feedback and focus group mechanism, this allows us to tailor the MOOC to patients even after the trial period is over. Allowing our patients to have increased self direction in the shared decision making process is also an added advantage. In addition, this would represent a cost effective and sustainable option for our department, reducing in the long term printed leaflet

Nationally/internationally
Regionally, this MOOC can be rolled out to other trusts/institutions offering the same surgery using a similar template that can be personalized for the individual trust/institution. Patient groups such

as Obesity UK can be approached to also give a seal of approval. This MOOC can also provide a template for expansion into other surgical areas such as pelvic floor surgery, elective colorectal resections, laparoscopic cholecystectomy, anti-reflux surgery and many other non time critical elective operations.

Dissemination of findings:

We aim to disseminate findings regionally through the north east bariatric symposium. This would allow us also to roll out the MOOC regionally in order to gain acceptance and uptake. Nationally and internationally, we aim to submit the study findings to BOMSS (British Obesity and Metabolic Surgical Society) meeting. We would also publish our study in a high impact bariatric or general surgical journal such as the British Journal of Surgery or Obesity Surgery. We would also want to get patient influence groups such as Obesity UK on board with this and ask them to promote the MOOC and also get their input. Once the trial phase is over, we can look at opening up the MOOC to a wider audience nationally and internationally.

References:

1. Royal College of Surgeons of England. Consent: supported decision-making. A guide to good practice. 2016.
2. De Mik SM, Stubenrouch FE, Balm R, Ubbink DT. Systematic review of shared decision-making in surgery. Journal of British Surgery. 2018 Dec;105(13):1721-30.
3. Ford KE, Cooper LR. Learning from lawsuits: ten-years of NHS litigation authority claims against 11 surgical specialities in England. The Surgeon. 2018 Feb 1;16(1):27-35.
4. Musbahi A, Brown LR, Reddy A, Viswanath YK, Rao M, Gopinath BR. Systematic review of online patient resources to support shared decision making for bariatric surgery. International Journal of Surgery. 2020 Feb 1;74:34-8.
5. Mazoue JG. The MOOC model: Challenging traditional education. EDUCAUSE review online. 2013 Jan;28.
6. Stathakarou N, Zary N, Kononowicz AA. Beyond xMOOCs in healthcare education: study of the feasibility in integrating virtual patient systems and MOOC platforms. PeerJ. 2014 Nov 13;2:e672.[1]